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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,586	04/24/2000	MAURIZIO VALLERI	515-4183	6516

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	**PAPER NUMBER**
1615	17

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/463,586	Applicant(s) VALLERI, MAURIZIO	
	Examiner Amy E Pulliam	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *9-12* is/are allowed.

6)☒ Claim(s) *1-8 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: Courtesy Copy

DETAILED ACTION

Receipt is acknowledged of the Extension of Time and the Amendment C, both received by the Office on December 9, 2002.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 2 724 844 to Meignant *et al.* in view of US Patent 5,576,021 to Andob *et al.* OR US Patent 4,493,822 to Tovey OR Remington's Pharmaceutical Sciences.

Meignant *et al.* disclose a therapeutic composition of vitamins and calcium, in the form of tablets, comprising elemental calcium and at least one vitamin D. Meignant *et al.* further teach that the calcium is present in salt form, and can be calcium carbonate, calcium pidolate, calcium chloride, calcium glycerophosphate, calcium lactate, calcium citrate, calcium gluconate or calcium phosphate (p 11, claim 2). Meignant *et al.* also teach that the vitamin D can be in the form of vitamin D_2 or D_3 (page 11, claim 3). Additionally, Meignant *et al.* teach the inclusion of well known excipients, such as binders, lubricants, diluents, and flavor agents (p 2, l 20-35). Meignant *et al.* also teach that the formulation can be in tablet or sachet form (p 13, claim 13). Lastly, Meignant *et al.* teach a process for making the formulation, including granulating the components and mixing them together, prior to making the final dosage form (p 13, claim 14).

Meignant *et al.* teach 1250 mg of calcium carbonate (which corresponds to 500 mg of elemental calcium) and 4 mg of vitamin D3 (which corresponds to 400 IU). This fulfills the ratio requirement of applicant's instant claim 1. The claim states that the calcium salt must be present in a ratio of 1-2 g of elemental calcium for each 500-1000 IU of vitamin D. Meignant *et al.* teach the identical ratio, as the amounts are simply divided by 2. Therefore, Meignant *et al.* teach the weight requirements of applicant's instant claims.

Meignant *et al.* do not teach each of the binders claimed by applicant. However, Meignant *et al.* do teach the presence of a very well known pharmaceutical binder, polyvinyl pyrrolidone.

Andoh *et al.*. teach an improved oral dosage form. This reference is relied upon for the teachings of equivalency between polyvinyl pyrrolidone and polyethylene glycol as tablet binders. See column 9, claim 4, and column 10, claim 12.

Additionally, Tovey teach pharmaceutical dosage units. Tovey is also relied upon for the teaching of equivalency between polyvinyl pyrrolidone and polyethylene glycol as tablet binders. See column 5, lines 1-13.

Additionally, Remington's Pharmaceutical Sciences discloses a list of binders to be used in pharmaceutical formulations. Remington's teaches polyvinyl pyrrolidone, polyethylene glycol, and waxes. It is the position of the examiner that the disclosure to waxes teaches the equivalency between PVP, PEG, and liquid paraffin. See page 1635, column 2, last 2 paragraphs.

It is the position of the examiner that absent comparative scientific data teaching otherwise, one of ordinary skill in the art would have been motivated to use any well known

tablet binder in the composition of Meignant *et al.*, with the same expected result, especially because Meignant *et al.* teach that their invention is useful for the same purpose of combating osteoporosis as applicant's composition. This is reiterated with the teachings of equivalency provided by Andoh *et al.*, Tovey, and Remington's. There has been no comparative evidence provided to convince the examiner that the use of one binder versus another would provide patentable distinction between the instant application and the cited prior art. The examiner recommends that applicant submit some evidence comparing the prior art to the instantly claimed formulation, in order to overcome this rejection. For the above reasons, this rejection would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant's arguments have been fully considered but are not found to be persuasive. Applicant argues that Meignant does not teach the amount of calcium and Vitamin D.claimed by Applicant, because Applicant's claims require a minimum amount of 500 I.U. of Vitamin D with a minimum amount of 1 g of calcium. The examiner directs Applicant's attention to page 7 –8 of the French document, or page 13 of the attached English translation. This portion of the cited reference teaches that the doses which can be generally used with respect to their invention include calcium in an elementary form, from about 500 mg to about 1500 mg, and vitamin D, or a mixture of vitamin Ds, from about 2 mg to about 12 mg. Therefore, the reference does teach Applicant's claimed minimum amount of vitamin D, as well as Applicant's claimed ratio, as discussed in the above rejection.

Applicant further argues that Meignant refers to pharmaceutical composition which must be prepared in a "humid environment." Referring to the attached English translation again, the examiner finds no teaching in claim 4 of the reference which requires a humid environment.

Applicant also asserts that the preferred calcium salt is calcium phosphate and its analogs. Applicant argues that Meignant does not teach the necessary limitations to have success with calcium phosphate. This argument is unpersuasive for two reasons. First, calcium phosphate is not a limitation in the independent claim, and therefore this argument is not commensurate in scope with all of the instant claims. Second, Meignant specifically teaches the use of calcium phosphate. Therefore, the reference is clearly suggestive of using this particular form of calcium.

Lastly, Applicant argues that the PEG cited by the examiner is not the same PEG cited by Applicant. It remains the position of the examiner, that absent evidence to the contrary, based on the teachings above, PEG is a well known excipient. The burden is shifted to Applicant to show unexpected results found when using a particular form of PEG. Any results should be in declaration form, with statistical analysis, and should rely solely on the particular form of PEG.

For these reasons, this rejection is maintained.

Allowable Subject Matter

Claims 9-12 are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
March 24, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600